Not for Publication

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, **Plaintiff,** **v.** **HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, HETERO DRUGS LIMITED, HETERO USA, INC., AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., AUROLIFE PHARMA LLC, EUGIA PHARMA SPECIALTIES LIMITED, APOTEX INC., APOTEX CORP., MYLAN PHARMACEUTICALS, INC., MYLAN INC., MYLAN, N.V., BRECKENRIDGE PHARMACEUTICAL, INC., and TEVA PHARMACEUTICALS USA, INC.,** **Defendants.**	**Civil Action No. 17-3387 (ES) (MAH)** **Consolidated** **OPINION**

SALAS, DISTRICT JUDGE

Before the Court is the parties' request for claim construction. The Court held a *Markman* hearing on January 30, 2020. (D.E. No. 621). This Opinion sets forth the Court's constructions of the disputed terms.

I. Background[1]

Plaintiff Celgene Corporation ("Celgene") brought these Hatch-Waxman Act patent infringement actions against defendants Hetero Labs Limited, Hetero Labs Limited Unit-V, Hetero

[1] The Court draws these facts from the parties' submissions and provides this background for contextual purposes only. Nothing in this section should be construed as a finding of fact by this Court.

Drugs Limited, Hetero USA, Inc. (together, "Hetero"), Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, Eugia Pharma Specialties Limited (together, "Aurobindo"), Apotex Inc., Apotex Corp. (together, "Apotex"), Mylan Pharmaceuticals, Inc., Mylan Inc., Mylan, N.V. (together, "Mylan"), Breckenridge Pharmaceutical, Inc. ("Breckenridge"), and Teva Pharmaceuticals USA, Inc. ("Teva") (collectively, "Defendants") relating to Celgene's drug product, Pomalyst®. (D.E. No. 348, Amended Joint Claim Construction Statement ("Am. Joint Stmt.")) at 2). Defendants collectively filed six Abbreviated New Drug Applications ("ANDA") with the Federal Drug Administration ("FDA"), seeking approval to market generic versions of Pomalyst. (*Id.*). Celgene alleges that Defendants' submissions of their respective ANDA constitute infringements of certain claims of Celgene's patents under 35 U.S.C. § 271(e)(2). (*Id.*). In response, Defendants allege that the asserted claims are invalid and/or not infringed. (*Id.*).

Celgene initially asserted ten patents against Defendants. (*See* D.E. No. 211 at 2 & Am. Joint Stmt. at 1). On January 22, 2019, the parties stipulated to bifurcate the case and stay the claims and proceedings regarding five of the ten patents that cover certain Risk Evaluation and Mitigation Strategy ("REMS") solutions. (D.E. No. 288). Shortly thereafter, on January 25, 2019, the parties stipulated to consolidation of the various cases against Defendants. (D.E. No. 294). The parties then amended their infringement contentions and non-infringement contentions, and, accordingly, amended their respective proposed terms for construction. (*See.* D.E. No. 320). The parties subsequently filed their Amended Joint Claim Construction and Prehearing Statement, identifying a total of seven disputed terms. (Am. Joint Stmt. at 4). While the request for claim construction was pending and prior to the *Markman* hearing, the parties resolved their disputes regarding the meaning of three terms. (D.E. No. 384 at 1 n.2 (Celgene withdrawing its opposition

to Teva, Mylan, Breckenridge, and Aurobindo's proposed construction for the term "total weight of the composition"); D.E. No. 615 (the parties agreeing that the Court need not construe the "pomalidomide" terms)).

Most recently, on April 27, 2020, the Court further consolidated with the instant action six cases in which Celgene asserted United States Patent No. 10,555,939 (the "'5,939 Patent"[2]) against Defendants. (D.E. No. 695). The parties agree that the '5,939 Patent is part of the same patent family of two patents that are already at issue in this instant case. (*Id.* at 3 (ECF Pagination)). The parties also agree that no additional claim construction proceedings are needed for this newly added patent. (*Celgene Corporation v. Apotex Inc.*, No. 20-2593, D.E. No. 15 at 4 (Celgene stating that "[t]he parties seem to agree that the claims of the ['5,]939 patent do not necessarily require additional fact discovery or *Markman* proceedings beyond what was done for the '467 patent in the -3387 Consolidated Action"); *id.* at 15 (Teva, Apotex, Aurobindo, and Hetero agreeing with Celgene's position); *id.* at 21 ("Breckenridge does not believe that claim construction proceedings are necessary in this case because the claims of the '[5,]939 patent are virtually identical to the claims of the '467 patent."); *id* at 22 ("Whether or not the case is consolidated with the -3387 Consolidated Action, the Mylan Defendants do not believe claim construction proceedings are necessary.")).

Accordingly, this *Markman* decision involves four disputed terms from six patents stemming from two patent families: (i) United States Patent No. 8,198,262 (the "'262 Patent"), United States Patent No. 8,673,939 (the "'3,939 Patent"), and United States Patent No. 8,735,428 (the "'428 Patent"), which are method of treatment ("MOT") patents; and (ii) United States Patent No. 8,828,427 (the "'427 Patent"), United States Patent No. 9,993,467 (the "'467 Patent"), and the

[2] Because this case involves United States Patent No. 10,555,939 and United States Patent No. 8,673,939, both of which end with "939," the Court will identify these two patents using their last four digits.

'5,939 Patent, which are formulation patents. (*See* Am. Joint Stmt. at 2; D.E. No. 695).

II. Legal Standard

A. Claim Construction

A patent claim is that "portion of the patent document that defines the scope of the patentee's rights." *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 321 (2015). When the parties in a patent infringement action "present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008). A district court's claim construction is reviewed de novo, but its underlying factual determinations (*i.e.*, determinations based on extrinsic evidence) are reviewed for clear error. *Teva Pharms*., 574 U.S. at 322.

The words of a claim are generally given their ordinary and customary meaning, which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). To determine the ordinary and customary meaning of a disputed term, the court must look to "those sources available to the public that show what a person of skill in the art would have understood [the] disputed claim language to mean." *Id.* at 1314.

"In determining the proper construction of a claim, the court has numerous sources that it may properly utilize for guidance. These sources . . . include both intrinsic evidence (*e.g.*, the patent specification and file history) and extrinsic evidence (*e.g.*, expert testimony)." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Thus, the court must "look to the claim language, the specification, the prosecution history, and any relevant extrinsic evidence." *Meyer Intellectual Props. Ltd. v. Bodum, Inc*., 690 F.3d 1354, 1368 (Fed. Cir. 2012).

With respect to intrinsic evidence, "the claims themselves provide substantial guidance as to the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314. Indeed, "the context in which a term is used in the asserted claim can be highly instructive." *Id.* Similarly, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term." *Id.*

The specification "is always highly relevant to the claim construction analysis" and "is the single best guide to the meaning of a disputed term." *Id.* at 1315. "[T]he specification may reveal a special definition given to a claim term by the patentee" or "may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Id.* at 1316. Thus, "the specification necessarily informs the proper construction of the claims," and it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Id.* at 1316–17. Notably, however, the court may "not read limitations from the specification into claims." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012). In particular, the Federal Circuit has "repeatedly warned against confining the claims to . . . embodiments" described in the specification. *Phillips*, 415 F.3d at 1323.

Courts must also consider the patent's prosecution history, *i.e.*, "the complete record of the proceedings before the PTO . . . includ[ing] the prior art cited during the examination of the patent." *Id.* at 1317. Although the prosecution history "often lacks the clarity of the specification and thus is less useful for claim construction purposes," it can nevertheless "inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

In sum, "[c]laim terms are given their ordinary and customary meaning—the meaning that they would have to a person of ordinary skill in the art in light of the specification and prosecution history at the time of the invention." *Woods v. DeAngelo Marine Exhaust, Inc.*, 692 F.3d 1272, 1283 (Fed. Cir. 2012). And, "[c]laim terms are properly construed to include limitations not otherwise inherent in the term only when a patentee sets out a definition and acts as his own lexicographer, or when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Id.* (internal quotation marks omitted); *see also Aventis Pharm. Inc. v. Amino Chems. Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013) ("The written description and other parts of the specification, for example, may shed contextual light on the plain and ordinary meaning; however, they cannot be used to narrow a claim term to deviate from the plain and ordinary meaning unless the inventor acted as his own lexicographer or intentionally disclaimed or disavowed claim scope.").

Finally, the court may also rely on extrinsic evidence, *i.e.*, "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317. But, extrinsic evidence "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1319.

B. Preamble

Whether to treat a preamble as a limitation "is determined on the facts of each case in light of the overall form of the claim, and the invention as described in specification and illuminated in the prosecution history." *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1572–73 (Fed. Cir. 1996). The key is to review the entire patent "to gain an understanding of what the inventors actually invented and intended to encompass by the claim."

Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting *Corning Glass Works v. Sumitomo Electric U.S.A., Inc.*, 868 F.2d 1251, 1257(Fed. Cir. 1989)).

"While there is no simple test for determining when a preamble limits claim scope," the Federal Circuit has set forth "some general principles to guide that inquiry." *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F. 3d 1354, 1358 (Fed. Cir. 2010). "Generally, . . . the preamble does not limit the claims." *Id.* "Preamble language that merely states the purpose or intended use of an invention is generally not treated as limiting the scope of the claim." *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 952 (Fed. Cir. 2006). But if a preamble "recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim," the preamble limits the invention. *Catalina*, 289 F.3d at 808 (internal quotation marks omitted). Specifically, "[w]hen limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention." *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1339 (Fed.Cir.2003). This is because such "antecedent basis" indicates "a reliance on both the preamble and claim body to define the claimed invention" and the preamble becomes "essential to understand limitations or terms in the claim body." *Catalina*, 289 F.3d at 808; *see also Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333 (Fed. Cir. 2003).

With regard to reviewing the preamble in light of the specification, the Federal Circuit has held that the preamble may operate as a claim limitation if it "recit[es] additional structure or steps underscored as important by the specification." *Catalina*, 289 F.3d at 808. However, "not every preamble reference to additional structure is limiting, even when the structure is noted in the specification." *Arctic Cat Inc. v. GEP Power Prod., Inc.*, 919 F.3d 1320, 1329 (Fed. Cir. 2019) (holding that the preamble is not limiting where the it does not supply "structure needed to make the body itself a 'structurally complete invention'" and "merely adds structure of which the body-

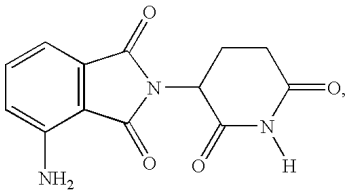
recited module is a part").

Finally, "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention." *Catalina*, 289 F.3d at 808. Conversely, "preamble language merely extolling benefits or features of the claimed invention does not limit the claim scope without clear reliance on those benefits or features as patentably significant." *Id.* at 809.

III. Analysis

A. Method of Treatment Patents

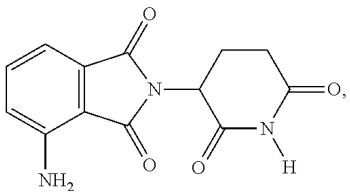
The '262 Patent, the '3,939 Patent, and the '428 Patent are method of treatment patents and claim methods of using pomalidomide to treat multiple myeloma. Claim 1 of the '262 Patent and Claim 26 of the '3,939 Patent are representative for both sets of disputed terms in the method of treatment patents family. Claim 1 of the '262 Patent claims:

> A method of treating multiple myeloma, which comprises administering to a patient having multiple myeloma: (a) from about 1 mg to about 5 mg per day of a compound having the formula:
>
> 
>
>
> or a pharmaceutically acceptable salt, solvate or stereoisomer thereof for 21 consecutive days followed by seven consecutive days of rest from administration of said compound in a 28-day cycle, and (b) 40 mg of dexamethasone.

Claim 26 of the '3,939 Patent claims:

> A method of treating multiple myeloma, which comprises administering to a patient having multiple myeloma, and which patient has received previous therapy for multiple myeloma and has demonstrated disease progression on the previous therapy, from

about 1 mg to about 5 mg per day of a compound having the formula:



or a solvate thereof, wherein the compound is administered in one or more cycles, each of which comprises administering the compound for a period of time followed by a period of rest.

1. "A method of treating multiple myeloma"[3]

Celgene	Defendants[4]	The Court
"A method of treating multiple myeloma" is limiting, such that the term requires efficacy in treating multiple myeloma.	"A method of treating multiple myeloma" is not limiting.	"A method of treating multiple myeloma" is not limiting.

The parties dispute whether the preamble of the method of treatment patents should be construed as limiting. Celgene argues that the phrase "treating multiple myeloma" in the preamble limits the claim by requiring efficacy in patients who received pomalidomide. (Celgene Open. Br. at 5). Defendants argue to the contrary. (Def. Open. Br. at 4). Before discussing the merits of the parties' arguments, the Court first addresses Defendants' argument regarding the proper test to apply to construe the preamble. At oral argument, Defendants argued for the first time that, in *Boehringer Ingelheim v. Schering-Plough*, 320 F. 3d 1339 (Fed. Cir. 2003), the Federal Circuit

[3] This disputed term appears in asserted claims 1–2, 4–16, 18–27, and 29 of the '262 Patent; claims 1–14 and 16–35 of the '3,939 Patent; and all claims of the '428 Patent. (Am. Joint Stmt. at 4).

[4] Apotex and Hetero initially proposed that the preamble is not limiting; but to the extent that the Court holds that the preamble is limiting, Apotex and Hetero proposed that the term should be construed as "[a] method of administering pomalidomide, or a pharmaceutically acceptable salt, solvate, stereoisomer thereof, after the onset of symptoms of multiple myeloma." (D.E. No. 251 ("Celgene Open. Br.") at 5). Apotex and Hetero have since withdrawn their alternative construction and joined the other defendants in their proposed claim construction. (D.E. No. 250 ("Def. Open. Br.") at 4 n.4).

laid out a two-step process where, first and foremost, the Court must apply the Federal Circuit's guidance and principles to decide whether a preamble is a limitation. (*See* D.E. No. 649 ("*Markman* Tr.") at 30:15–23 & 32:2–12). Counsel further argued that "if, and only if" the Court finds that the preamble is a limitation, the Court then construes what the preamble means. (*Id.* at 32:13–33:11). The Court agrees that, in *Boehringer*, the Federal Circuit first affirmed that the disputed term in the preamble imposed a limitation on the claim, then concluded that the district court also "gave the term its proper construction." 320 F. 3d at 1345. But nothing in *Boehringer* suggests that the Federal Circuit established an analytic framework under which courts must construe a preamble. *See generally id*. It certainly makes sense to use the two-step analysis, when, for example, finding that a disputed term imposes a limitation does not resolve the parties' dispute. *See, e.g.*, *Boehringer*, 320 F.3d at 1345–56; *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366 (Fed. Cir. 2008). However, where, as here, the analyses of whether the preamble is limiting and what the preamble means are necessarily intertwined, neither the Federal Circuit nor the district courts have construed the disputed terms using such a rigid multi-step test. *See, e.g.*, *Symantec Corp. v. Computer Assocs. Int'l, Inc.*, 522 F.3d 1279, 1289–90 (Fed. Cir. 2008) (construing the terms in the preamble before holding that the preamble does not impose a separate claim limitation); *Sanofi-Aventis U.S. LLC v. Fresenius Kabi USA, LLC*, No. 14-7869, 2016 WL 5898627 (D.N.J. Oct. 7, 2016) (spontaneously construing the preamble language and analyzing whether it is limiting). The Court will thus analyze the disputed preamble language based on "the facts of [the] case in light of the overall form of the claim, and the invention as described in the specification and illuminated in the prosecution history." *Applied Materials*, 98 F.3d at 1573.

Defendants argue that courts around the country have found that the plain and ordinary meaning of the word "treating" means "to seek cure or relief of" a disease. (*See Markman* Tr. at

24:10–26:17). According to Defendants, "treating" is "a broader concept than just efficacious treatment," and includes ineffective treatment and palliative care where the treatment targets the symptoms and not the underlying condition. (*Id.* at 25:17–21). Defendants point out that the specification supports this broader concept and states that "[a]s used herein, unless otherwise specified, the term 'treating' refers to the administration of a compound of the invention or other additional active agent after the onset of symptoms of the particular disease or disorder." (Def. Open. Br. at 8 (quoting '262 Patent at 16:11–15)[5]).

Celgene does not appear to dispute that the plain and ordinary meaning of the word "treating" includes more than efficacious treatment but argues that the specification's definition of "treating" does not define the disputed phrase "a method of treating multiple myeloma." (D.E No. 384 ("Celgene Resp. Br.") at 6–7). Celgene contends that "treating" and "multiple myeloma" cannot be construed separately. (*See* Celgene Resp. Br. at 7). Rather, the full phrase, "treating multiple myeloma," was used throughout the prosecution history to require efficacy, without which "the invention would lose its entire purpose." (*See id.* & Celgene Open. Br. at 7).

While the Court agrees that the disputed term, "treating multiple myeloma," must be construed in its entirety, nothing in the claim language, the specification, or the prosecution history warrants reading into the claim an efficacy limitation based on the preamble. The Court begins its claim construction with the language of the claim. *See Innova/Pure Water, Inc. v. Safari Water filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004) ("Claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to particularly point out and distinctly claim the subject matter which the patentee regards as his

[5] The parties agree that the '262 Patent, the '3,939 Patent, and the '428 Patent share a common specification. (Celgene Open. Br. at 7 n. 9; Defs. Open. Br. at 5 n.7). For the sake of brevity, the Court's citations to the specification of the '262 Patent include the corresponding citations to the '3,939 Patent and the '428 Patent.

invention.") (internal quotation marks and alterations omitted). It is important to note that the parties do not dispute that the preamble does not provide any antecedent basis for terms in the body of the claim. (Def. Open. Br. at 5–8; *Markman* Tr. at 10:17–21). While Celgene argues that the patentability of the MOT claims "hinge[s] upon" the presence of the preamble in the claim language, Celgene's argument is not grounded in the language of the claim itself. (*See* Celgene Open. Br. at 11–12). For example, this is not a case where the preamble "sets forth the objective of the method, and the body of the claim directs that the method be performed on someone 'in need.'" *Jansen*, 342 F.3d at 1333; *see also Rapport v. Dement*, 254 F.3d 1053, 1059 (Fed. Cir. 2001). Nor does Celgene argue that a term used in the preamble provides antecedent basis because the same term is used in the body of the claim. *See Pacing Techs., LLC v. Garmin Int'l, Inc.*, 778 F.3d 1021, 1024 (Fed. Cir. 2015). Indeed, Celgene advances no argument based on the language of the claims. The Court thus agrees with Defendants that the claim language strongly suggests that the preamble is independent from, and not limiting to, the body of the claim, and the steps of the claimed method at issue are "performed in the same way regardless whether or not the patient experiences [any efficacy]." *See Bristol-Myers Squibb Co. v. Ben Venue Labs, Inc.*, 246 F.3d 1368, 1375 (Fed. Cir. 2001).

The Court is also not persuaded that statements in the specification identified by Celgene compel a finding that that the preamble at issue here sets forth "the essence or a fundamental characteristic[s] of the claimed invention[s]." (*See* Celgene Open. Br. at 10). Celgene points to the "Background" section of the specification, which identifies "a significant need for safe and ***effective*** methods of treating, preventing and managing cancer . . . , particularly for diseases that are refractory to standard treatments . . . ." (*Id.* at 7 (quoting '262 Patent at 3:8–11) (emphasis Celgene's)). The specification then states, under "Summary of the Invention," that "[t]he methods

comprise administering to a patient in need of such treatment or prevention a ***therapeutically or prophylactically effective*** amount of an immunomodulatory compound, or a pharmaceutically acceptable [alternative] thereof." (*Id.* at 8 (quoting '262 Patent at 3:41–47) (emphasis Celgene's)). Celgene further points to various places in the specification where the patentee discusses combination therapies, dosing cycles, and examples in terms of efficacy. (*Id.* at 8–9). In response, Defendants essentially argue that, if efficacy is a "fundamental or essential feature" of the invention, the patentee could have drafted the claims to require efficacy or included clinical data to substantiate it. (D.E. No. 385 ("Def. Resp. Br.") at 11–12).

The cases Defendants rely on do not support the proposition that efficacy, as a fundamental or essential feature, must be supported by clinical data. *See Hoffman-La Roche Inc. v. Apotex Inc.*, 748 F.3d 1326, 1331 (Fed. Cir. 2004). However, the Court agrees that the statements in the specification merely stated that the intended use or purpose of the claimed invention is to achieve "safe and effective" treatment. None of the cited portions of the specification suggests that efficacious treatment is a limitation of the claims. *See Sanofi-Aventis*, 2016 WL 5898627 at *5 (finding that the preamble "a method of increasing the survival" is not limiting and that the specification's statement that "an aspect of the invention comprises increasing the survival of a patient [at issue] . . . merely appears to describe the purpose of the invention"); *Novartis Pharmaceuticals Corp. v. Accord Healthcare Inc.*, 387 F. Supp. 3d 429, 437–38 (D. Del. 2019) (holding that the efficacy is not a limitation despite the patentee's argument that efficacy is "the core of the invention" and where the specification stated that "there is a need for agents which are effective in the inhibition or treatment of . . . multiple sclerosis").

Moreover, nothing in the specification supports Celgene's argument that "treating" and "multiple myeloma" are so "inextricably intertwined" such that it is inappropriate to construe the

entire phrase by construing "treating" separately. (*See* Celgene Resp. Br. at 7). Other than in the claims, "treating multiple myeloma" appears only in the patent's title. ('262 Patent at 1:1–2). Where the specification discusses "multiple myeloma" or "patients with multiple myeloma," the words "treat," "treating," or "treatment" are either not used, or are used without an efficacy requirement. *See, e.g.*, '262 Patent at 18:24–27 ("In a specific embodiment, [Actimid™] may be *administered* in an amount of about 1, 2, or 5 mg per day to patients with relapsed multiple myeloma.") (emphasis added); *id.* at 19:34–37 ("In a specific embodiment, Revimid™ is *administered* to patients with relapsed or refractory multiple myeloma in an amount of about 15 mg/d twice a day or about 30 mg/d four times a day in a combination with dexamethasone.") (emphasis added); *id.* at 33:44–46 ("Once the [maximum tolerance dose] has been identified, four additional patients are enrolled at that dose level so that a total of 10 patients is *treated* at the MTD."); *id.* at 35:53–54 ("In this study, the first cohort of 3 patients was *treated* for 28 days at 5 mg/day without any dose limiting toxicity . . . ."). The Court thus finds that nothing in the specification compels a finding that the patentee intended "treating multiple myeloma" to deviate from the plain and ordinary meaning of the term "treating," such that the claims require efficacy.

Celgene also argues that the preamble is limiting because "it is the basis upon which the Patent Office allowed the claims." (Celgene Open. Br. at 11). During the prosecution of the '3,939 Patent and the '428 Patent, the patentee submitted evidence of "unexpected results" to overcome an obviousness rejection and argued that "one skilled in the art would not have expected that pomalidomide would be able to *treat multiple myeloma* that is relapsed after or refractory to prior treatment." (D.E. No. 251-3, Ex. 10 ("Celgene Ex. 10") at CELPOM00001074 (emphasis Celgene's); *id.*, Ex. 11 at CELPOM000001375) (emphasis Celgene's)). In a subsequent Applicant-Initiated Interview Summary, the Examiner essentially agreed with the patentee and

stated that "the claims, as is, are patentable because pomalidomide (POM) alone was shown to unexpectedly *treat multiple myeloma* that is or has become resistant to lenalidomide (LEN), a structurally close analog of POM that is known to be effective for *treating multiple myeloma*." (*Id.*, Ex. 12 at CELPOM00001113). Celgene thus argues that the prosecution history shows that "the claims issued only because the inventors demonstrated to the Examiner that their invention was efficacious against" multiple myeloma. (Celgene Open. Br. at 12). Celgene further argues that, when the patentee and the Examiner referred to "'treat[ing] multiple myeloma' in the prosecution history, they meant that pomalidomide was providing efficacy against" multiple myeloma. (*Id.*).

Defendants argue that the "unexpected results" cannot define the scope of the claims because: (i) the data was generated after the priority date; (ii) the "unexpected results" were not commensurate in scope with the claimed invention; (iii) the unexpected results were never submitted in the '262 Patent, which is the first patent issued in the family; and (iv) Celgene did not present the "unexpected results" as a necessary feature of the invention, but merely as a result of carrying out the claimed methods. (Def. Resp. Br. at 4–5 & 8–11).

The Court finds merit in Defendants' argument that reliance on unexpected results to show nonobviousness does not limit or otherwise define the scope of the claim. *See Takeda Pharm. Co. v. Actavis Labs. FL, Inc.*, No. 15-451, 2016 WL 3193188, at * (D. Del. June 6, 2016) (stating that unexpected results "do not define the claimed invention in any real respect—they merely state one of the intended results or purposes of the claimed invention"); *Viiv Healthcare UK Ltd. v. Lupin Ltd*,, 904 F. Supp. 2d 379, 386–87 (D. Del. 2012) (holding that, unlike arguments made to overcome rejection of anticipation, unexpected results submitted and argued to prove nonobvious did not "require the claims to be narrowed, distinguished, or amended"); *McNeil-PPC, Inc. v.*

Perrigo Co., 443 F. Supp. 2d 492, 505 (S.D.N.Y. 2006) (stating that the courts cannot "mechanically import limitations from the [unexpected] test results into the claims"). The argument is particularly strong here because the unexpected results were generated after the priority date. (*See* Def. Resp. Br. at 4). But more importantly, the Federal Circuit's *en banc* opinion in *Purdue Pharma L.P. v. Endo Pharm. Inc.* is directly on point. 438 F.3d 1123 (Fed. Cir. 2006). There, in response to an obviousness rejection, the patentee told the PTO that its claimed oxycodone formulation was distinguishable from the prior art because the patentee had "surprisingly discovered" that the four-fold range of dosages achieves the same clinical results as the prior art formulation using an eight-fold range. *See id.* at 1130. Based on this "discovery," which overcame the obviousness rejection, the trial court construed the claims to be "limited to a four-fold dosage range that controls pain for 90% of patients." *Id*. at 1135. The Federal Circuit disagreed and held that the four-fold range was not a "necessary feature of the claimed oxycodone formulations." *Id.* at 1136. Rather, the court explained that the four-fold range was "a property of, or a result of administering, the oxycodone formulation characterized" by the limitations set forth in the body of the claims. *Id.* Similarly here, the unexpected efficacious treatment of relapsed or refractory multiple myeloma with pomalidomide was merely a "result of administering" the claimed invention. Celgene thus fails to distinguish *Purdue* and establish that the prosecution history demonstrates that the patentee intended efficacy to be a "necessary feature" of the claimed methods. *See id.*; *Sanofi-Aventis*, 2016 WL 5898627, at *6 (holding that "[w]hile the Examiner noted the unexpected result in allowing the patent, [p]laintiffs have failed to show that the claims require the unexpected results").

Moreover, the Court is not persuaded that the inventors consistently used "treat[ing] multiple myeloma" in the prosecution history to mean efficacious treatment. (Celgene Open. Br.

at 12). As evidence to support the "unexpected results," Celgene submitted to the Patent Office a declaration by Dr. Anjan Thakurta during the prosecution of the '3,939 Patent. (D.E. No. 250-11 at 75 (ECF Pagination)[6]). Dr. Thakurta explained the results of Phase I and Phase II clinical studies where patients with relapsed or refractory multiple myeloma were treated with single-agent pomalidomide in a cyclic regimen as recited in the claims of the '3,939 Patent. (*Id.* at 76). Dr. Thakurta further stated that, based on these clinical data, the FDA "has approved the use of pomalidomide alone for *treating patients with multiple myeloma*," where such condition was relapsed or refractory. (*Id.* at 76–77) (emphasis added). Thus, as used in the very declaration Celgene relied on to prove unexpected efficacy, the phrase "treating patients with multiple myeloma" clearly did not require efficacy—it is insensible to understand the statement to mean that the FDA only approved the use of pomalidomide when it efficaciously treated patients. Therefore, contrary to Celgene's argument, the applicant does not consistently use "treating [patients with] multiple myeloma" to mean efficacious treatment, and it is thus improper to import an efficacious limitation from the prosecution history into the claims. *See Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1360 (Fed. Cir. 2004) ("the patent applicant's consistent usage of a term in prosecuting the patent may enlighten the meaning of that term."); *Purdue*, 428 F. 3d at 1136–37.

Finally, as the other example that applicant clearly relied on the preamble to distinguish prior art during prosecution, Celgene refers to arguments made during the prosecution of the '262 Patent. (Celgene Resp. Br. at 9). Specifically, Celgene explains that the Examiner rejected all pending claims for obviousness over the combination of three prior art references: United States Patent No. 5,635,517 (the "'517 Patent"), an article dubbed "Davies," and United States Patent

[6] Unless stated otherwise, the Court's citations to the prosecution history refer to the pagination generated by the Court's ECF system.

No. 6,555,554. (D.E. No. 250-3 at 27). To overcome the obviousness rejection, the applicant argued that, *inter alia*, the Examiner's reliance on Davies is misplaced because Davies would not motivate a POSA to choose more potent TNF-α inhibitors, such as pomalidomide, to treat multiple myeloma. (*Id.*). The applicant submitted publications to show that "potent known TNF-α inhibitors failed in *treating multiple myeloma*." (*Id.*) (emphasis added). The applicant further stated that, for example, Enbrel®, which is a well-known TNF-α inhibitor, "did not have anti-myeloma activity. Thus, not all TNF-α inhibitors *treat multiple myeloma*." (*Id.*). Based on these statements, Celgene argues that the applicant "relied on the express language of the preamble in disclaiming ineffective treatments from the scope of the claimed inventions." (Celgene Resp. Br. at 9).

In response, Defendants urge that the Federal Circuit has established a high standard for "clear reliance" on preamble, where, after the applicant disparaged the prior art, the applicant must "put their hands on the preamble" and argue that, "by contrast," the claimed invention is distinct. (*Markman* Tr. at 82:3–20 & 84:8–85:25). Defendants argue that, because the applicant only used the preamble language to characterize the prior art, without relating back to the claimed invention, it was insufficient to find "clear reliance" on the preamble such that the preamble imports an efficacy limitation. The Court is not persuaded that the law requires such a formalistic approach. The cases Defendants rely on only show that "clear reliance on the preamble" was found where the applicant explicitly distinguished the claimed invention after disparaging the cited reference. *See, e.g.*, *Roundtable Techs. LLC v. Motorola Mobility LLC*, 567 Fed. Appx. 941, 943 (Fed. Cir. 2014).

The Court agrees, however, that Celgene fails to establish clear reliance on the preamble because the applicant's arguments made to distinguish the prior art were insignificant to

patentability. Indeed, when the Examiner withdrew the obviousness objection, he stated that "[a]pplicant's arguments, see page 7, 2nd full paragraph, filed 12/23/2010, with respect to the rejections of the claims under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn." (D.E. No. 250-4 at 28). In the paragraph the Examiner referenced, the applicant argued that another prior art reference, the '517 Patent, was also misplaced because it does not disclose "the treatment of multiple myeloma with thalidomide and dexamethasone, much less the cyclical treatment." (*Id.* at 54). In other words, the applicant overcame the obviousness rejection based on arguments that were irrelevant to Davies, to efficacious treatment, or to arguments made based on the preamble to distinguish Davies. Because the applicant's argument invoking the preamble had no bearing on the Examiner's decision to withdraw the obviousness rejection, the efficacy requirement that purportedly distinguished Davies and other TNF-α inhibitors was insignificant for patentability. Thus, the applicant's reliance on the preamble to distinguish prior art does not amount to clear reliance, nor does it compel reading an efficacy limitation into the claim. *See Catalina*, 289 F. 3d at 810 (holding that, where the Examiner considered the feature recited in the preamble insignificant for patentability, the applicant's statements distinguishing the prior art based on such feature "do not indicate a clear reliance on the preamble").

For the foregoing reasons, the Court adopts Defendants' proposed construction and holds that the preamble of the claims in the MOT patents, "a method of treating multiple myeloma," is not limiting.

2. "about 1 mg to about 5 mg per day of a compound having the formula [of pomalidomide] or a pharmaceutically acceptable salt, solvate, or stereoisomer thereof" and "about 1 mg to about 5 mg of a compound having the formula [of pomalidomide] or a

solvate thereof"[7]

Celgene	Defendants	The Court
"about 1 mg to about 5 mg per day of a compound having the formula [of pomalidomide] or a pharmaceutically acceptable salt, solvate, or stereoisomer containing about 1 mg to about 5 mg per day of a compound having the formula [of pomalidomide]"	"about 1 mg to 5 mg ... of a compound having the formula [of pomalidomide] or about 1 mg to 5 mg of a pharmaceutically acceptable salt or solvate of [pomalidomide] or about 1 mg to 5 mg of any single stereoisomer of [pomalidomide]"	"about 1 mg to about 5 mg per day of a compound having the formula [of pomalidomide] or a pharmaceutically acceptable salt, solvate, or stereoisomer containing about 1 mg to about 5 mg per day of a compound having the formula [of pomalidomide]"
and	and	and
"about 1 mg to about 5 mg per day of a compound having the formula [of pomalidomide] or a solvate containing about 1 mg to about 5 mg per day of a compound having the formula [of pomalidomide]"	"about 1 mg to 5 mg ... of a compound having the formula [of pomalidomide] or about 1 mg to 5 mg of a solvate of [pomalidomide]"	"about 1 mg to about 5 mg per day of a compound having the formula [of pomalidomide] or a solvate containing about 1 mg to about 5 mg per day of a compound having the formula [of pomalidomide]"

The MOT patents claim methods of treatment using pomalidomide compound in its free base form, as well as pomalidomide in the form of "a pharmaceutically acceptable salt, [ ] solvate, [or] stereoisomer." *See, e.g.*, '262 Patent, Claim 1. When the drug is a pharmaceutically acceptable salt or solvate of pomalidomide, the active moiety of the drug, which is the portion that is responsible for the physiological or pharmacological action, remains the same. However, depending on the weight of the additional molecules that are added to the active moiety, the overall weight of pomalidomide salt and pomalidomide solvate varies. The parties thus dispute whether the weight requirement in the disputed terms, "about 1 mg to 5 mg," applies to the active moiety

[7] These disputed terms appear in asserted claims 1–2, 4–16, 18–27, and 29 of the '262 Patent; claims 1–14 and 16–35 of the '3,939 Patent; and all claims of the '428 Patent. (Am. Joint Stmt. at 4).

only (as Celgene proposes), or to the entire pomalidomide salt and pomalidomide solvate (as Defendants propose). (*See, e.g.*, Def. Open. Br. at 12; Celgene Open. Br. at 14).

Celgene argues that the word "thereof" in the disputed terms refers back to everything that precedes the word 'or', which includes the specifically claimed amounts of pomalidomide. (Celgene Open. Br. at 14; Celgene Resp. Br. at 13). Accordingly, Celgene contends that the claims are directed to the use of "salt, solvate, or stereoisomer of pomalidomide that is equivalent to the about 1 mg to about 5 mg of pomalidomide free base." (Celgene Resp. Br. at 13). Defendants, on the other hand, rely on the word "or" in the disputed terms, and argue that it "identif[ies] different, alternative forms for the active ingredient." (Def. Open. Br. at 13). According to Defendants, "about 1 mg to about 5 mg refers to the amount of each of the claimed forms of pomalidomide, including pomalidomide free base, pomalidomide salt, pomalidomide solvate, and a single pomalidomide stereoisomer." (Def. Resp. Br. at 18). Essentially, under Celgene's proposed construction, the claims are directed to treatment using the same dose of active moiety, regardless of the form of the drug (*i.e.*, free base, salt, solvate, or isomers). To the contrary, under Defendants' proposed construction, the claims are directed to treatment using varying amounts of active moiety, because the total weight of the drug remains the same regardless of the drug form.

The Court agrees with Celgene. Defendants essentially argue that a plain reading of the claims support their construction, because the word "or" identifies "different, alternative forms of the active ingredient," to which "about 1 mg to 5 mg" must be applied equally. (Def. Open. Br. at 12–13 ("Defendants' proposed constructions merely follow the language of the claims by stating that the 'about 1 mg to about 5 mg' weight limitation applies to the alternative forms of the administered drug . . . ."); Def. Resp. Br. at 18 ("Defendants' proposed construction is based on a plain reading of the unambiguous language of the claims.")). But an "ordinary meaning" of a

claim term is merely a "short-hand for the appropriate connotation under the law: the meaning, to a person of ordinary skill in the art." *See Combined Sys., Inc. v. Def. Tech. Corp. of Am.*, 350 F.3d 1207, 1216 n.6 (Fed. Cir. 2003) (citing *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir 2002)). Absent certain established exceptions, and Defendants have argued none, "a plain and simple reading" of the claim terms cannot deviate from the "objective base line from which to begin claim interpretation;" that is, "how a person of ordinary skill in the art understands a claim term." *See Phillips*, 415 F.3d at 1313.

Here, Defendants' own expert, Dr. Kinam Park, agreed during a deposition that a person of ordinary skill in the art ("POSA") would understand that "in pharmacotherapeutics, it is the pharmacologically active moiety of a drug compound that is responsible for the therapeutic response." (D.E. No. 384-1, Ex. 26 ("Park Depo. Tr.") at 108:11–20). Here, that pharmacologically active moiety is the pomalidomide, and "specifically, the free base of pomalidomide." (*Id.* at 109:12–19). Dr. Park further agrees that a POSA would understand that when "a different form of a drug is used to satisfy formulation requirements[,] the quantity of the pharmacologically active drug moiety is maintained at the desired therapeutic dose or concentration." (*Id.* at 110:14–111:7). Dr. Park further opined, and the Court agrees, that "nothing in the specifications of the MOT patents indicates that the calculations should be performed contrary to accepted practice in the field." (D.E. No. 250-32 ("Park Decl.") ¶ 61). Thus, based on Dr. Park's own opinion, the standard practice in the field is that the same amount of pharmacologically active moiety must be administered to a patient, regardless of whether the drug is in the form of a salt, solvate, or stereoisomer.

This construction is supported by other extrinsic evidence, including evidence Dr. Park references to demonstrate what a POSA would consider as "relevant and reflective of the state of

prior art at the time" of the invention. (Park Decl. ¶ 59 & D.E. No. 250-39). For example, based on the 2010 Ansel textbook titled "Pharmaceutical Calculations" ("2010 Ansel"), among others, Dr. Park stated that "it is the standard practice to take into account the weight of the entire compound, including the weight of the proton and counterion or solvent molecules, when the active moiety is described as taking the form of a salt or solvate." (Park Decl. ¶ 59). Similarly, to support that the weight requirement of the claims applies to the entire molecule, Defendants emphasized that pharmaceutical calculations must "account for the active ingredient, or active moiety, and water content of drug substances." (Def. Open. Br. at 14–15). However, 2010 Ansel itself states that, as "objectives" of calculation of active drug moiety,

> [a] pharmacist must be able to calculate the pharmacologically active drug (chemical) moiety when present in salt, ester, hydrated, or complex chemical form. Such calculations are essential when quantitatively comparing products of the same drug moiety but differing in chemical form. The calculations are applied in compounding procedures in which *a different form of a drug is used to satisfy formulation requirements while the quantity of the pharmacologically active drug moiety is maintained at the desired therapeutic dose or concentration.*

(D.E. No. 250-39 ("Park Decl. Ex. 7") at 325) (emphasis added). In other words, Defendants' own extrinsic evidence shows that, by "taking into account" the molecular weight of the entire molecule of different drug products, the objective of pharmaceutical calculation is, indeed, to maintain the same therapeutic dose or concentration. That is, to maintain the same amount of active drug moiety.

Finally, Defendants argue that "stereoisomer" should be construed to mean "any single stereoisomer." (Def. Open. Br. at 15). According to Defendants, the chemical structure of pomalidomide free base as depicted in the disputed terms already includes combinations of stereoisomers; a POSA thus would have understood the portion of the claim that involves "stereoisomer" to mean "about 1 mg or 5 mg of any single stereoisomer." (*Id.*). Celgene proposes

no construction for this term and provides no support for its position, except for referencing "stereoisomer" along with "salt" and "solvate" and arguing that "the claims call for treatment with about 1 [mg] to about 5 mg of pomalidomide itself, regardless of whether the pomalidomide is in the form of a salt, solvate, or stereoisomer." (Celgene Open. Br. at 13–15; *see also* Celgene Resp. Br. at 13–14).

Nevertheless, the Court is not persuaded by Defendants' argument. The parties do not appear to dispute that stereoisomers are molecules with the same molecular formula and sequence of bonded atoms but differ in the three-dimensional orientations of their atoms in space. (*See* Celgene Open. Br. at 49; Park Decl. ¶¶ 36–39). It is also seemingly undisputed that the chemical structure depicted in the disputed terms encompasses combinations of stereoisomers of pomalidomide. *See, e.g.,* '262 Patent at 11:43–46 ("if the stereochemistry of a structure or a portion of a structure is not indicated with, for example, bold or dashed lines, the structure or portion of the structure is to be interpreted as encompassing all stereoisomers of it."). The Court thus finds that there does not appear to be a dispute among the parties and that the meaning of "stereoisomer" is clear and needs no construction. *Vivid Techs., Inc. v. Am. Science & Eng'g, Inc.*, 200 F. 3d 795, 803 (Fed. Cir. 1999) (stating that "only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy").

For the foregoing reasons, the Court adopts Celgene's proposed construction, which is supported by the claim language and is consistent with the standard industry practice.

B. Formulation Patents

1. "Lubricant"

Celgene	Teva and Aurobindo	Apotex	The Court
"a substance capable of reducing friction and/or reducing adhesion"	"an excipient, in addition to the binder or filler, having the primary function of reducing	Requires no construction	"a substance capable of reducing friction and/or reducing adhesion"

	friction and/or reducing adhesion beyond the level achieved by other excipients (i.e. carrier, diluent, binder or filler)"

The '427 Patent, the '467 Patent, and the '5,939 Patent claim pharmaceutical formulations containing pomalidomide. The disputed term "lubricant" appears in Claims 6 to 8 of the '467 Patent, as well as Claims 6 to 8 of the '5,939 Patent. Claims in the '467 Patent are representative, where Claim 1, the only independent claim, recites the following:

> 1. An oral dosage form in the form of a capsule which comprises: 1) pomalidomide at an amount of 0.1 to 3 weight percent of the total weight of the composition; 2) a binder or filler at an amount of 90 to 99 weight percent of total weight of the composition, wherein the binder or filler is a mixture of starch and mannitol; and
>
> wherein the ratio of mannitol:starch in the dosage form is from about 1:1 to about 1:1.5.

Claims 6 to 8 then claim "[the] oral dosage form of claim 1 further comprising a lubricant at an amount of" varying weight percent of total weight of the composition. '467 Patent, Claims 1 & 6–8.

The dispute with regard to the construction of "lubricant" is mainly between Teva and Aurobindo, on the one hand, and Celgene, on the other; while Apotex believes that no construction is necessary, and Breckenridge, Hetero, and Mylan take no position as to the construction of this term. (*See* D.E. No. 349 ("Celgene Supp. Open. Br.") at 8–11; D.E. No. 350 at 2; D.E. No. 351 ("Teva Supp. Open. Br.") at 10–18; D.E. No. 354 at 7). Teva and Aurobindo argue that the "further comprising" language in Claims 6 to 8 indicates that "'lubricant' must . . . be a distinct and additional component" relative to the "binder or filler." (Teva Supp. Open. Br. at 12). For support, Teva and Aurobindo cite to the specification and prosecution history of the '467 Patent and argue that the patentee "consistently characterizes the invention as dosage forms containing

pomalidomide and 'excipients [which] comprise a carrier, diluent, binder, or filler ***and*** a lubricant.'" (*Id.* at 14) (emphasis Teva and Aurobindo's). In other words, Teva and Aurobindo argue that, by referring to excipients as either a "binder or filler" or a "lubricant," an excipient cannot function both as a "binder or filler" and a "lubricant". (*Id.* at 12–13). A "lubricant," according to Teva and Aurobindo, is "a separate and distinct excipient, the primary function of which is to lubricate." (*Id.* at 15–16).

Celgene, on the other hand, does not dispute that Claims 6 to 8 of the '467 Parent require a lubricant *in addition to* a binder or filler. (*See, e.g.*, *Markman* Tr. at 145:19–23 (counsel for Celgene stating that "Claim 6 adds a further limitation that requires the presence of an additional functional ingredient. So it does add that there has to be a lubricant in the formulation.")). Yet Celgene contends that the phrase "further comprising" only requires "additional recited *elements*," as opposed to "a distinct and additional component." (Celgene Resp. Br. at 25–26). According to Celgene, the "additional recited elements" added in Claims 6 to 8 are the "specific weight percentage of the lubricant." (*Id.* at 26). Celgene states that "as long as the required weight percentage of one structural inactive ingredient is functioning as a binder/filler, and the other claimed weight percentage of that same structural inactive ingredient is functioning as a lubricant, the claims are met." (*Id.*).

The Court agrees with Celgene. This is a situation where "the claims themselves provides substantial guidance" as to the meaning of the term "lubricant." *See Philips*, 415 F.3d at 1314. The "further comprising" language in Claims 6 to 8 requires that the "lubricant" must be an additional component relative to "binder or filler." As Teva and Aurobindo correctly point out, the Federal Circuit and this Court have recognized that the phrase "further comprising" indicates that the elements following the phrase "further comprising" are not part of the limitations

preceding that phrase. *See David Netzer Consulting Eng'r LLC v. Shell Oil Co.*, 824 F.3d 989, 996 (Fed. Cir. 2016); *Purdue Pharm. Prod. L.P. v. Actavis Elizabeth LLC*, 12-5311, 2015 WL 5032650, at *13 (D.N.J. Aug. 25, 2015). This is especially true where, as here, the patentee uses the word "wherein" in other dependent claims to indicate that patentee's intention to narrow the meaning of the "binder/filler." For example, Claim 3 of the '467 patent reads: "The oral dosage form of claim 1, ***wherein*** the binder or filler is present at an amount of 95 to 99 weight percent of total weight of the composition." Claim construction principles thus dictate that, for example, Claim 6 must include all limitations of Claim 1 *and* "a lubricant at an amount of 0.01 to 1 weight percent of the total composition." Teva and Aurobindo are thus correct in that Claims 6 to 8 "add an additional element required to be present in an infringing product: a lubricant." (*See* Teva Supp. Br. at 13).

However, nothing in the specification or the prosecution history supports Teva and Aurobindo's proposition that the "lubricant" has to be a substance that is "distinct from" a binder or filler. The specifications Teva and Aurobindo cite to are merely examples where the lubricant used is a different substance from the binder or filler. (*See, e.g.*, '467 Patent at 7:52–62, 8:21–31, 8:57–67, 9:26–36, 9:62–10:5 & 10:30–40). Similarly, language from prosecution history only shows that the patentee intended the claimed formulations to comprise excipient or excipients of *different functions*. (*See, e.g.*, D.E. No. 355-4 at CELPOM12428172–74). None of the evidence supports that the patentee intended that these different functions necessarily be served by different substances. Therefore, "it is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited." *Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1327 (Fed. Cir. 2012)

Because Teva and Aurobindo do not argue, nor could they, that the intrinsic evidence reveals "an intentional disclaimer, or disavowal, of claim scope by the inventor," the Court thus agrees with Celgene that a single excipient, as disclosed in the '467 Patent and the '5,399 Patent, can serve different functions. Accordingly, the Court also rejects Teva and Aurobindo's position that a lubricant must have a primary function of lubricating.

For the foregoing reasons, the Court adopts Celgene's proposed construction of "lubricant".

IV. Conclusion

The Court will construe the disputed terms as explained above. An appropriate Order accompanies this Opinion.